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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | |
|--|--------------------------|----------------------|---------------------|------------------|--|
| 09/754,010 | 01/03/2001 | Mark E. Dillon | E-1950 | 3438 | |
| John F. A. Earle | 7590 07/21/201 ey III | 1 | EXAM | INER | |
| 86 The Commons At Valley Forge East | | | PURDY, KYLE A | | |
| 1288 Valley Forge Road P.O. Box 750 | | ART UNIT | PAPER NUMBER | | |
| Valley Forge, P | A 19482-0750 | | 1611 | | |
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| | | | 07/21/2011 | PAPER | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | Application No. | Applicant(s) | |
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| | 09/754,010 | DILLON, MARK E. | |
| Office Action Summary | Examiner | Art Unit | |
| | KP | 1611 | |
| The MAILING DATE of this communication ap Period for Reply | ppears on the cover sheet w | rith the correspondence address | · |
| A SHORTENED STATUTORY PERIOD FOR REP WHICHEVER IS LONGER, FROM THE MAILING I - Extensions of time may be available under the provisions of 37 CFR 1 after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period Failure to reply within the set or extended period for reply will, by statu Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | DATE OF THIS COMMUN 1.136(a). In no event, however, may a d will apply and will expire SIX (6) MO ute, cause the application to become A | ICATION. reply be timely filed NTHS from the mailing date of this communic BANDONED (35 U.S.C. § 133). | |
| Status | | | |
| 1) ■ Responsive to communication(s) filed on <u>5/6</u> 2a) ■ This action is FINAL . 2b) ■ Th 3) ■ Since this application is in condition for allow closed in accordance with the practice under | is action is non-final. ance except for formal ma | · | ts is |
| Disposition of Claims | | | |
| 4) ☐ Claim(s) 34-36,38,39 and 41-54 is/are pendir 4a) Of the above claim(s) 46-54 is/are withdra 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 34-36, 38, 39 and 41-45 is/are reject 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and | awn from consideration. | | |
| Application Papers | | | |
| 9) The specification is objected to by the Examir 10) The drawing(s) filed on is/are: a) acceptable and applicant may not request that any objection to the Replacement drawing sheet(s) including the correct 11) The oath or declaration is objected to by the Examir 11. | ccepted or b) objected to e drawing(s) be held in abeya ection is required if the drawing | nce. See 37 CFR 1.85(a). g(s) is objected to. See 37 CFR 1.11 | ` . |
| Priority under 35 U.S.C. § 119 | | | |
| 12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of: 1. Certified copies of the priority document 2. Certified copies of the priority documents. Copies of the certified copies of the priority documents. See the attached detailed Office action for a list | nts have been received. nts have been received in a light in the ligh | Application No n received in this National Stage | 9 |
| Attachment(s) | _ | | |
| 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date | Paper No | Summary (PTO-413) (s)/Mail Date Informal Patent Application | |

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DETAILED ACTION

Status of Application

- 1. The Examiner acknowledges receipt of the arguments filed on 5/6/2011.
- 2. Claim 40 has been cancelled.
- 3. Claims 34-36, 38, 39 and 41-45 are presented for examination on the merits. The following rejections are made.

Response to Applicants' Arguments

- 4. Applicants arguments filed 5/6/2011 regarding the rejection of claims 34-36, 38, 39 and 41-45 made by the Examiner under 35 USC 103(a) over Freeman et al. (US 5681579) in view of Lorenz et al. (US 5258421), evidenced by US 4832009 have been fully considered but they are not found persuasive and is **MAINTAINED** for the reasons of record in the office action mailed on 11/2/2010.
 - 5. In regards to the 103(a) rejection, Applicant asserts the following:
- **A)** The references do not teach a dual-purpose wound dressing wound dressing having both a first wound contacting side and a second wound contacting side.
- 6. In response to A, Applicant is arguing an intended use for their product, where the product being claimed is structurally suggested by the art. Freeman provides a multi-layer wound dressing that possesses a first and a second layer where the <u>first layer</u> comprises a hydrocolloid and a polymeric material such as polyurethane and a <u>second layer</u> which is occlusive and is to be a polyurethane foam. Lorenz is cited to show that polyurethane polymer present in the first layer may be substituted with silicone-polytetrafluoroethylene IPN. With respect to the first and second layers having distinct wound healing properties and having both first and second wound

contacting sides, these properties would necessarily be present in the obvious structure provided

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by the combination of Freeman and Lorenz. Applicants argument is not persuasive.

Maintained Rejections, of Record

Claim Rejections - 35 USC § 103

- 7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 8. Claims 34-36 and 38-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Freeman et al. (US 5681579; of record) in view of Lorenz et al. (US 5258421; of record), evidenced by US 4832009 (of record).
- 9. Freeman discloses a polymeric support wound dressing (see abstract). Figure 1 discloses the occlusive layer (11) (second layer) bonded by adhesives (13) means to a hydrocolloid containing polymeric layer (12) (first layer).



The occlusive layer 11 has an upper or outer surface 14, which is open to the atmosphere and an inner surface 13 which faces the skin. The occlusive layer is preferably a polyurethane foam (see column 4, lines 30-31). The adhesive layer may for example extend across the entire under surface 13 of the occlusive layer or only a portion of it. The polymeric support layer 12 is any polymeric material useful in medical settings and is in the form of a web, net, perforated film or

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perforated layer. The polymeric support layer 12 contains a hydrocolloid blended with the polymeric material wherein the polymeric material is polyurethane (see column 1, lines 10-20). It should be noted that a membrane is defined as a "thin, soft pliable sheet or layer"; thus Freeman's polymeric support reads on instantly claimed "membrane layer". The polymeric support layer is 0.5-3 mils (35 microns to 76 microns). See column 4, lines 5-8. The adhesive layer is made of various substances including silicone rubber (see column 6, line 31).

- 10. Freeman does not teach the use of instant silicone-polytetrafluoroethylene IPN membrane layer or a pigment.
- 11. Lorenz et al teaches a hydrophilic gel dressing (see abstract). Lorenz teaches coating a gel layer on a backing substrate that provides liquid barrier properties and may be a polymer film such as polyurethane. The polymer film may also be silicone-polytetrafluoroethylene IPN membrane. Lorenz teaches silicone-polytetrafluoroethylene has particular utility in wound dressing because it retains moisture and excess exudate is absorbed to promote healing (see column 5, lines 50-68). When the backing substrate is of the instant silicone-polytetrafluoroethylene, the structure is also useful as a burn blanket (see 5, lines 30-33 and column 6, lines 28-30). Additionally, the backing substrate may be covered by a silicone-coated release-liner. Various conventional additives such as pigments and dyes in the gels are contemplated (see column 4, lines 49-55).
- 12. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Freeman with the teaching of Lorenz such that the polymeric material in the membrane layer of Freeman is replaced by the silicone-polytetrafluoroethylene IPN polymer taught as by Lorenz with a reasonable expectation for

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success in improving the wound healing characteristics of the wound dressing of Freeman. One would have been motivated to use the IPN polymer of Lorenz as it's taught that IPN has beneficial barrier properties for improving wound healing by keeping the moisture in, preventing bacteria from entering the wound and absorbing the excess exudates. Therefore, a skilled artisan would have been motivated to utilize the instant polymer film (IPN) in the wound dressing over Freeman's polyurethane film for the advantages taught by Lorenz, i.e. if one desired to provide a structure that also promoted healing by preventing re-infection, i.e. by preventing bacteria from entering the wound site.

13. With regard to claim 41, it is noted that polymeric film layers are implicitly translucent unless a pigment is added. Further, it should be noted that US '009 substantiates the examiner's position that the silicone-polytetrafluoroethylene IPN are transparent. Note column 1, lines 55-60 of US '009. Thus, thus reads on "substantially transparent". Further, polyurethane foams are implicitly opaque. With regard to the addition of pigment to the adhesive layer, it is considered prima facie obvious to add a pigment to any layer to distinguish each layer. It should be noted that the instantly claimed aesthetic design change does not impart patentable significance with regard to the mechanism in which the wound article functions.

Conclusion

- 14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).
- 15. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing

date of this final action.

16. Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Kyle A. Purdy whose telephone number is 571-270-3504. The

examiner can normally be reached from 9AM to 5PM.

17. If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Sharmila Landau, can be reached on 571-272-0614. The fax phone number for the

organization where this application or proceeding is assigned is 571-273-8300.

18. Information regarding the status of an application may be obtained from the Patent

Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR

system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/K Purdy/

Examiner, Art Unit 1611

July 13, 2011

/Allison M. Ford/

Primary Examiner, Art Unit 1653